Guidance on Neurological Embolization Devices (DRAFT)
Questions on Clinical Trials Proposal

1. For embolization devices, there are a number of neurologic and functional status tools that can be used for clinical studies. Among these are the World Federation of Neurosurgeons grade (WFNS), Glasgow Outcome Scale (GOS), Glasgow Coma Scale (GCS), NIH Stroke Scale, and the Barthel Index. Please discuss the strength and weaknesses of these assessment tools and comment on the conditions under which each would be appropriate to use.

2. For embolization devices, there are a number of potential imaging tools that can be used for clinical studies. Angiography, MRI, MRA and/or CT are the current imaging methods utilized for the pre and post operative assessment of patients. Please discuss the strengths and weaknesses of these imaging tools and comment on any population dependence and on the appropriate times these tools should be utilized.

3. Because reader bias of angiograms/scans can affect the analysis of data, FDA believes the inclusion of masked readers of angiograms/scans, unlabeled control angiograms/scans within the series of scans, or centralized reading of angiograms/scans could be used to minimize bias. Please discuss the strengths and weaknesses of these masking techniques and comment on how each method may be used in the assessment of embolization devices.

4. Currently, for pre-surgery embolization patients, the guidance document suggests several endpoints related to the surgical procedure, i.e., surgical time and/or blood loss. Please comment on these clinical measurements and any others that are important for the evaluation of surgical risk. Please also discuss any measurement tools that can be used for these assessments.

5. For arteriovenous malformations (AVMs) collateral vessel formation around embolized lesions has been documented and is a concern. Please discuss and comment on how and when collateral vessel formation can be evaluated.

6. FDA is recommending 1-year follow-up in clinical trials for patients intended for permanent embolization. In the guidance document, 1-year follow-up is recommended with a MRI/CT scan and neurologic evaluation. Please comment on whether there should be additional long-term follow-up and what data should be gathered long-term.